



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,411	08/03/2000	Xu Cao	D6258	9593

7590 12/26/2001
Benjamin Aaron Adler
McGregor & Adler LLP
8011 Candle Lane
Houston, TX 77071

EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 12/26/2001

h

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/631,411

Applicant(s)

CAO ET AL.

Examiner

Ram R. Shukla, Ph.D

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

1. Claims 1-20 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-6 and 15-20, drawn to a method of regulating bone formation and gene expression by providing an individual a transgene expressing Smad6, classified in class 514, subclass 44.
- II. Claims 1-6 and 15-20, drawn to drawn to a method of regulating bone formation and gene expression by providing an individual an antisense molecule directed towards Smad6, classified in class 514, subclass 44.
- III. Claims 1-6 and 15-20, drawn to drawn to a method of regulating bone formation and gene expression by providing an individual an antibody binding to Smad6 to Hox protein, classified in class 424, subclass 184.1.
- IV. Claims 7 and 8, drawn to an in vitro method of screening for compounds that disrupt transcriptional repression of a gene by combining Smad6 and Hox proteins and a candidate compound, classified in class 435, subclass 7.1.
- V. Claims 9 and 10, drawn to a method of screening for a compound that disrupts transcriptional repression of a gene by determining the binding of a protein to a DNA in the presence of a candidate compound in vitro, classified in class 435, subclass 6.
- VI. Claims 11 and 12, drawn to a method for screening of compounds that disrupt transcriptional repression by assaying transcription of the gene in the presence of a candidate compound, classified in class 435, subclass 6.

3. The embodiments recited in claims 2, 5, and 18 are common to the inventions of the groups I-III. Should any of these groups be elected, claims 2, 5, and 18 would be examined to the extent they read on the elected invention.

4. Claims 3, 6, and 16 are generic to a plurality of disclosed patentably distinct species comprising osteopontin, osteoprotegrin, OPGL, and RANK. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Claim 12 is generic to a plurality of disclosed patentably distinct species comprising a northern blot assay, a western blot assay, an enzymatic assay and a chemiluminiscent assay. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. The inventions are distinct, each from the other because of the following reasons:

Inventions of the groups I to VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

Art Unit: 1632

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods that use different steps or different components. For example, the methods of the groups I-III are directed to methods that would be carried out in an animal and therefore, their steps would be distinct from those of the groups IV-VI that would be carried out in vitro. Furthermore, the methods of the groups I-III are distinct each from the other because they use different compositions that have different properties and their mode of administration as well as effects would be different. For example, the method of administering a nucleic acid would be different from that of an antibody. Likewise the methods of the groups IV-VI are distinct each from the other because the methods of the groups V and VI require a DNA while that of group IV does not require a DNA molecule. Furthermore, the method of group VI further requires a step of assaying transcription while no such step is required in the methods of groups IV and V. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

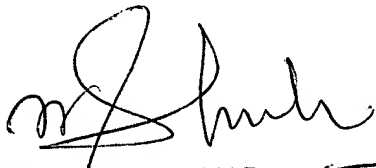
Applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c) and a copy of all the

Art Unit: 1632

pending/under consideration claims. For instructions, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Kay Pinkney whose telephone number is (703) 305-3553.

Ram R. Shukla, Ph.D.


RAM R. SHUKLA, PH.D
PATENT EXAMINER